Attorney Docket No.: 208-022US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mary Aldritt
Serial No.: 10/759,892
Filed: January 16, 2004
Customer No.: 27791
Title: EFFERVESCENT COMPOSITION INCLUDING CRANBERRY EXTRACT

Art Unit: 1655
Examiner: Hoffman
Confirmation No.: 8476

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF KYLE M. JOHNSON

I, Kyle M. Johnson, state and declare as follows:

1. I am a Development Scientist at Amerilab Technologies, Inc.

2. I have read and am familiar with AU 200157788 A1.

3. I prepared a cranberry fruit extract effervescent tablet according to the instructions set forth on pages 12-14 of AU 200157788 A1, with the following exceptions:

a) instead of using a cranberry 25:1 fruit extract, I used a cranberry 18:1 fruit extract because I was not able to obtain a cranberry 25:1 fruit extract;

b) instead of using powdered blackcurrant flavor, I used a spray dried, powdered cherry flavor, because, based on the information provided in AU 200157788 A1, I believed that it would behave similarly to the blackcurrant flavor;

c) instead of using a two speed planetary mixing blade and a separate horizontally mounted high speed chopper mixer, I used a Kitchen Aid mixer due to the amount of material used in forming the tablets. The Kitchen Aid has a planetary mixing action; therefore, I expected it to mix the composition in a manner similar to that of the described mixer. The absence of the chopping action did not appear to affect how well the materials blended; and

CERTIFICATE OF TRANSMISSION
I hereby certify under 37 CFR §1.8(a) that this correspondence is being electronically transmitted to the United States Patent and Trademark Office, by EFS-Web, on March 13, 2009.

Signature
Allison Johnson
Typed or Printed Name of Person Signing Certificate

d) I prepared the tablets in an environment controlled for humidity and temperature.

I do not believe that these changes increased the disintegration time of the resulting tablets.

4. The tablets that I prepared had the composition set forth in the table below.

Component	Amount (mg)/Tablet
Citric Acid	1100.00
Fumaric Acid	70.00
Polydimethylsiloxane	20.00
Lactose	1451.00
Sodium bicarbonate	800.00
Calcium carbonate	200.00
Cranberry 18:1 Fruit extract	200.00
Polyethylene glycol 6000	60.00
Cherry flavor	50.00
Polyvinylpyrrolidone	40.00
Sucralose	9.00
Total	4000.00

5. I first attempted to tablet the composition on a Cad Machine single compression roll tablet press using a one inch (i.e., 25.4 mm) diameter coated-flat faced tool. These tablets had an average mass of 3.97 g, an average thickness of 0.228 in, and an average hardness of 4.2 kiloponds (kp). I observed that three out of six of these tablets, i.e., 50 % of the tablets, exhibited capping.

6. I then adjusted the tablet press in an attempt to stop the tablet capping. The second set of tablets had an average hardness of 5.2 kp with a maximum tablet hardness of about 5.6 kp. I observed light filming on the tablet tools. These tablets also had an average mass of 3.99 g and an average thickness of 0.228 in.

7. I placed one of the tablets having an average hardness of 5.2 kp in a vessel that included eight ounces of water having a temperature of 71.9°F and observed the time

it took for the tablet to completely disintegrate. I repeated this for a second tablet. I observed the first tablet to completely dissolve in approximately 200 seconds and the second tablet to completely dissolve in 195 seconds. There were no particles present in either of the resulting liquids.

8. The difference between a disintegration time of less than 150 seconds and a disintegration time of 195 seconds for an effervescent tablet is statistically significant.

9. AU 2001157788 discloses that the tablet press used was a Jenn-Chiang Model JC-SH-31 tableting machine, which is a two roller press in which there is a pre-compression roller and a compression roller. Based on my experience, tablets made on a two roller press can be tableted to a greater hardness than tablets made on a single roller press. Based on my experience, harder tablets take longer to disintegrate than softer tablets of the same formulation. In my opinion, if the tablets had been made on a Jenn-Chiang Model JC-SH-31 tableting machine they could have been tableted to a greater hardness.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under section 1001 Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent on which this statement is directed.

Further I declare not.

Date: 03/11/09

Kyle M. Johnson

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